"*Bent beam linear accelerator*" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

"*Contact therapy system*" means a therapeutic radiation machine with a short target-to-skin distance (TSD), usually less than 5 centimeters.

"*Dose monitor unit (DMU)*" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

"*External beam radiation therapy*" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"*Field flattening filter*" means a filter used to homogenize the absorbed dose rate over the radiation field.

"*Filter*" means material placed in the useful beam to change beam quality or its intensity profile in therapeutic radiation machines.

"*Gantry*" means that part of a radiation therapy system supporting and allowing movements of the radiation head around a center of rotation.

"*Interruption of irradiation*" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"*Isocenter*" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

"*Megavolt (MV) (mega electron volt (MeV))*" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1 million volts in a vacuum. (Note: Current convention is to use MV for photons and MeV for electrons.)

"*Monitor unit (MU).*" See "Dose monitor unit."

"*Moving beam radiation therapy*" means radiation therapy with continuous displacement of one or more mechanical axes relative to the patient during irradiation. It includes arc therapy, skip therapy, conformal therapy and rotational therapy.

"*Nominal treatment distance*" means:

1. For electron irradiation, the distance from the scattering foil, or exit window, of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.
2. For X-ray irradiation target to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

"*Periodic quality assurance check*" means a procedure which is performed to ensure that a previous calibration continues to be valid.

"*Practical range of electrons*" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung X-rays. A further explanation may be found in "Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" (Medical Physics 18(1): 73-109, Jan/Feb 1991) and ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV," International Agency on Radiation Units and Measurements, September 15, 1984.

"*Radiation field.*" See "Useful beam."

"*Radiation head*" means the structure from which the useful beam emerges.

"*Radiation therapy physicist*" means an individual qualified in accordance with 41.3(6).

"*Redundant beam monitoring system*" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a preselected number of dose monitor units.

"*Shadow tray*" means a device attached to the radiation head to support auxiliary beam blocking material.

"*Stationary beam radiation therapy*" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

"*Target*" means that part of an X-ray tube or accelerator onto which is directed a beam of accelerated particles to produce ionizing radiation or other particles.

"Tenth-value layer (TVL)" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

"Therapeutic radiation machine" means X-ray or electron-producing equipment designed and used for external beam radiation therapy.

"Virtual source" means a point from which radiation appears to originate.

41.3(3) Registration or license requirements. No person shall receive, possess, use, transfer, own, or acquire therapeutic radiation machines except as authorized in a registration issued pursuant to 641—39.1(136C) to 39.4(136C).

41.3(4) General administrative requirements for facilities using therapeutic radiation machines.

a. Administrative controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines which have been registered with the agency. The registrant or the registrant's agent shall ensure that the requirements of 41.3(136C) are met in the operation of the therapeutic radiation machine(s).

b. A therapeutic radiation machine which does not meet the provisions of these regulations shall not be used for irradiation of patients unless authorized by the agency.

41.3(5) Training for external beam radiation therapy authorized users. The registrant for any therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall require the authorized user to be a physician who:

a. Is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology; or

(2) Radiation oncology by the American Osteopathic Board of Radiology; or

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

b. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

c. To satisfy the requirement for instruction in 41.3(5)*"b"* above, the classroom and laboratory training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of ionization radiation; and

(4) Radiation biology.

d. To satisfy the requirement for supervised work experience in 41.3(4)*"b"* above, training shall be under the supervision of an authorized user and shall include:

(1) Reviewing the full calibration measurements and periodic quality assurance checks;

(2) Evaluating prepared treatment plans and calculation of treatment times/patient treatment settings;

(3) Using administrative controls to prevent misadministrations;

(4) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(5) Checking and using radiation survey meters.

e. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

(1) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

(2) Selecting proper dose and how it is to be administered;

(3) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress; consideration of the need to modify originally prescribed doses or treatment plans as warranted by patients' reaction to radiation; and

(4) Postadministration follow-up and review of case histories.

f. Notwithstanding the requirements of 41.3(5)*"b,"* the registrant for any therapeutic radiation machine subject to 41.3(17) and 41.3(18) may also submit the training of the prospective authorized user physician for agency review.

41.3(6) Training for radiation therapy physicist. The registrant for any therapeutic radiation machine subject to 41.3(17) or (18) shall require the radiation therapy physicist to:

a. Be registered with the agency, under the provisions of 641—subrule 39.3(3) of these regulations, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and

b. Be certified by the American Board of Radiology in:

(1) Therapeutic radiological physics; or

(2) Roentgen-ray and gamma-ray physics; or

(3) X-ray and radium physics; or

(4) Radiological physics; or

c. Be certified by the American Board of Medical Physics in radiation oncology physics; or

d. Be certified by the Canadian College of Medical Physics; or

e. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full-time training in therapeutic radiological physics and also one year of full-time work experience under the supervision of a radiation therapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 41.3(16)*"a,"* 41.3(17)*"c"* and *"d,"* and 41.3(18)*"e"* and *"f"* under the supervision of a radiation therapy physicist during the year of work experience.

f. Rescinded IAB 4/3/02, effective 5/8/02.

41.3(7) Qualifications of operators.

a. Individuals who will be operating a therapeutic radiation machine for medical use shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment in accordance with 641—Chapter 42 as applicable.

b. Each operator's permit to practice under 641—Chapter 42 shall be posted in the immediate vicinity of the general work area and visible to the public.

41.3(8) Written safety procedures and rules shall be developed by a radiation therapy physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine.

41.3(9) Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a physician. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing arts purposes.

41.3(10) Records of visiting authorized users. Notwithstanding the provisions of 41.3(5), a registrant may permit any physician to act as a visiting authorized user under the following conditions:

a. The authorized user has the prior written permission of the registrant's management if the use occurs on behalf of an institution, and

b. The registrant maintains copies of all records specified in 41.3(5) for five years from the date of the last visit.

41.3(11) Information and maintenance record and associated information. The registrant shall maintain the following information for each therapeutic radiation machine for inspection by the agency:

a. Report of acceptance testing;

b. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by 41.3(136C), as well as the name(s) of person(s) who performed such activities;

c. Records of maintenance or modifications, or both, performed on the therapeutic radiation machine after July 9, 1997, as well as the name(s) of person(s) who performed such services;

d. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

e. Records of training specified in 41.3(5) and 41.3(6).

41.3(12) Records retention. All records required by 641—41.3(136C) shall be retained until disposal is authorized by the agency unless another retention period is specifically authorized in 41.3(136C). All required records shall be retained in an active file from at least the time of generation until the next agency inspection. Any required record generated before the last agency inspection may be microfilmed or otherwise archived as long as a complete copy can be retrieved until such time the agency authorizes final disposal.

41.3(13) Form of records. Rescinded IAB 4/5/00, effective 5/10/00.

41.3(14) Written directives. Each registrant shall meet the following:

a. A written directive must be dated and signed by an authorized user prior to the administration of radiation.

(1) If, because of the patient's condition, a delay in the order to provide a written revision to an existing directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

(2) The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

(3) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the external beam dose, or the next fractional dose.

(4) The registrant shall retain a copy of the written directive for three years.

b. Procedures for administration. The registrant shall have written procedures that provide the following information:

(1) Prior to the administration of each course of radiation treatment, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

(2) Each administration is in accordance with the written directive;

(3) External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives by:

1. Checking both manual and computer-generated dose calculations to verify that they are correct and in accordance with the written directive; and

2. Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

(4) Any unintended deviation from the written directive is identified, evaluated and appropriate action is taken; and

(5) The registrant retains a copy of the procedures for administrations for the duration of the registration.

41.3(15) Reports and notifications of misadministrations.

a. A registrant shall report any event resulting from intervention of a patient or human research subject in which the administration of external beam radiation results, or will result, in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

b. Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which the administration of an external beam radiation therapy dose results in:

(1) A dose that differs from the prescribed dose by more than 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin, and either:

1. The total dose delivered differs from the prescribed dose by 20 percent or more; or

2. The fractionated dose delivered differs from the prescribed dose for a single fraction by 50 percent or more.

(2) A dose that exceeds 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin from either of the following:

1. An administration of the wrong treatment modality;

2. An administration to the wrong individual or human research subject.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 sievert) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive.

c. The registrant shall notify the agency by telephone no later than the next calendar day after the discovery of a misadministration.

d. The registrant shall submit a written report to the agency within 15 days after the discovery of a misadministration. The written report shall include:

(1) The registrant's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

(5) The effect, if any, on the individual or individuals who received the misadministration;

(6) Actions, if any, that have been taken, or are planned, to prevent recurrence;

(7) Certification that the registrant notified the individual or the individual's responsible relative or guardian, and if not, why not.

e. The report to the agency shall not contain the individual's name or any other information that could lead to the identification of the individual.

f. The registrant shall provide notification of the event to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that the referring physician will inform the individual or that, based on medical judgment, the physician's telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant shall notify the individual as soon as possible thereafter. The registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event may be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

g. Aside from the notification requirement, nothing in this subrule affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the misadministration, or to individuals' responsible relatives or guardians.

h. A copy of the record required in this subrule shall be provided to the referring physician, if other than the registrant, within 15 days after discovery of the misadministration.

i. Records of misadministrations. A registrant shall retain a record of misadministrations reported in this subrule for three years. The record must contain the following:

(1) The registrant's name and the names of the individuals involved;

(2) The social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration;

(3) A brief description of the event; why it occurred; and the effect, if any, on the individual;

(4) The actions, if any, taken or planned to prevent recurrence; and

(5) Whether the registrant notified the individual or the individual's responsible relative or guardian, and, if not, whether such failure to notify was based on guidance from the referring physician.

41.3(16) General technical requirements for facilities using therapeutic radiation machines.

a. Protection surveys.

(1) The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed, are performed with an operable radiation measurement survey instrument calibrated within the past 12 months. The radiation protection survey shall be performed by, or under the direction of, a radiation therapy physicist or a certified health physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

1. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 641—subrule 40.15(1); and

2. Radiation levels in unrestricted areas do not exceed the limits specified in 641—paragraphs 40.26(1)*"a"* and *"b."*

(2) In addition to the requirements of 41.3(16)*"a"*(1), a radiation protection survey shall also be performed prior to medical use and:

1. After making any change in the treatment room shielding;

2. After installing or relocating of the therapeutic radiation machine;

3. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(3) The survey record shall indicate all instances where the facility, in the opinion of the radiation therapy physicist or a certified health physicist, is in violation of applicable regulations. The survey record shall also include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the therapeutic radiation machine, the instrument(s) used to measure radiation levels, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts or millirems per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the individual responsible for conducting the survey.

(4) If the results of the surveys required by 41.3(16)*"a"*(1) or (2) indicate any radiation levels in excess of the respective limit specified in 41.3(16)*"a"*(1), the registrant shall lock the control in the "OFF" position and not use the unit:

1. Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

2. Until the registrant has received a specific exemption in writing from the agency.

b. Modification of radiation therapy unit or room before beginning a treatment program. If the survey required by 41.3(16)*"a"* indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 641—paragraphs 40.26(1)*"a"* and *"b,"* before beginning the treatment program the registrant shall:

(1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 641—paragraphs 40.26(1)*"a"* and *"b"*;

(2) Perform the survey required by 41.3(16)*"a"* again; and

(3) Include in the report required by 41.3(16)*"d"* the results of the initial survey, a description of the modification made to comply with 41.3(5)*"b"*(1), and the results of the second survey; or

(4) Request and receive written authorization from the agency that authorizes radiation levels in unrestricted areas greater than those permitted by 641—paragraphs 40.26(1)*"a"* and *"b."*

c. Dosimetry equipment.

(1) The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration.

1. For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60.

2. For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured.

(2) The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 41.3(16)*"c"*(1)**.** This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in 41.3(16)*"c"*(1).

(3) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license or registration. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 41.3(16)*"c"*(1) and (2), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a radiation therapy physicist.

d. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall furnish a copy of the records required in 41.3(16)*"a"* and *"b"* to the agency within 30 days following completion of the action that initiated the record requirement.

41.3(17) Therapeutic radiation machines of less than 500 kV.

a. Equipment requirements.

(1) Leakage radiation. When the X-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

1. 5-50 kV systems. The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly shall not exceed 100 mrad (1 mGy) in any one hour.

2. >50 and <500 kV systems. The leakage air kerma rate measured at a distance of one meter from the target in any direction shall not exceed 1 rad (1 cGy) in any one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly shall not exceed 30 rad (30 cGy) per hour.

3. For each therapeutic machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at positions specified in 41.3(17)*"a"*(1)"1" and 41.3(17)*"a"*(1)"2" for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the facility for inspection by the agency.

(2) Permanent beam-limiting devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

(3) Adjustable or removable beam-limiting devices.

1. All adjustable or removable beam-limiting devices, diaphragms, cones or blocks shall not transmit more than 5 percent of the useful beam for the most penetrating beam used;

2. When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

(4) Filter system. The filter system shall be so designed that:

1. Filters cannot be accidentally displaced at any possible tube orientation;

2. For equipment installed after July 9, 1997, an interlock system prevents irradiation if the proper filter is not in place;

3. The air kerma rate escaping from the filter slot shall not exceed 1 rad (1 cGy) per hour at one meter under any operating conditions; and

4. Each filter shall be marked as to its material of construction and its thickness.

(5) Tube immobilization.

1. The X-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

2. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

(6) Source marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

(7) Beam block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(8) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

1. A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time or time remaining indicator;

2. The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

4. The timer shall permit accurate presetting and determination of exposure times as short as one second;

5. The timer shall not permit an exposure if set at zero;

6. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

7. Timer shall be accurate to within 1 percent of the selected value or one second, whichever is greater.

(9) Control panel functions. The control panel, in addition to the displays required by other provisions in 41.3(6), shall have:

1. An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible;

2. An indication of whether X-rays are being produced;

3. Means for indicating X-ray tube potential and current;

4. The means for terminating an exposure at any time;

5. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

6. For therapeutic radiation machines manufactured after July 9, 1997, a positive display of specific filter(s) in the beam.

(10) Multiple tubes. When a control panel may energize more than one X-ray tube:

1. It shall be possible to activate only one X-ray tube at any time;
2. There shall be an indication at the control panel identifying which X-ray tube is activated; and
3. There shall be an indication at the tube housing assembly when that tube is energized.

(11) Target-to-skin distance (TSD). There shall be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

(12) Shutters. Unless it is possible to bring the X-ray output to the prescribed exposure parameters within five seconds after the X-ray "ON" switch is energized, the beam shall be attenuated by a shutter(s) having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter(s) shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

(13) Low filtration X-ray tubes. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

b. Facility design requirements for therapeutic radiation machines capable of operating in the range 50 kV to 500 kV. In addition to shielding adequate to meet requirements of 41.3(8), the treatment room shall meet the following design requirements:

(1) Aural communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel.

(2) Viewing systems. Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(3) Additional requirements. Treatment rooms which contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

1. All protective barriers shall be fixed except for entrance doors or beam interceptors;
2. The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;
3. Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and
4. When any door referred to in 41.3(17)"*b*"(3)"3" is opened while the radiation machine is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

c. Full calibration measurements.

(1) Full calibration of a therapeutic radiation machine subject to 41.3(17) shall be performed by, or under the direct supervision of, a radiation therapy physicist:

1. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;
2. At intervals not exceeding one year; and

3. Before medical use under the following conditions:

- Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled; and
- Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

4. Notwithstanding the requirements of 41.3(17)*"c"*(1):

- Full calibration of therapeutic radiation machines with multienergy capabilities is required only for those modes or energies that are not within their acceptable range; and
- If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in 41.3(17)*"b"*(3).

(2) To satisfy the requirement of 41.3(17)*"c"*(1), full calibration shall include all measurements recommended for annual calibration by NCRP Report 69, "Dosimetry of X-ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).

(3) The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the X-ray tube, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the radiation therapy physicist responsible for performing the calibration.

d. Periodic quality assurance checks.

(1) Periodic quality assurance checks shall be performed on therapeutic radiation machines, subject to 41.3(17), which are capable of operation at greater than or equal to 50 kV.

(2) To satisfy the requirement of 41.3(17)*"d"*(1), quality assurance checks shall meet the following requirements:

1. The registrant shall perform quality assurance checks in accordance with written procedures established by the radiation therapy physicist; and

2. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in 41.3(17)*"c"*(1). The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in 41.3(17)*"c"*(1), shall be stated.

(3) The cause for a parameter exceeding a tolerance set by the radiation therapy physicist shall be investigated and corrected before the system is used for patient or human research subject irradiation;

(4) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the radiation therapy physicist's quality assurance check procedures, the system shall be recalibrated as required in 41.3(17)*"c"*(1);

(5) The registrant shall use the dosimetry system described in 41.3(16)*"c"*(2) to make the quality assurance check required in 41.3(17)*"d"*;

(6) The registrant shall have the radiation therapy physicist review and sign the results of each radiation output quality assurance check within one month of test completion;

(7) The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to 41.3(17) are performed at intervals not to exceed one month;

(8) Notwithstanding the requirements of 41.3(17)*"d"*(6) and (7), the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by 41.3(17)*"d"*(6) and (7) have been performed within the 30 days prior to administration;

(9) To satisfy the requirement of 41.3(17)*"d"*(7), safety quality assurance checks shall ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;
2. Proper operation of the "BEAM-ON" and termination switches;
3. Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;
4. Viewing systems;
5. If applicable, electrically operated treatment room doors from inside and outside the treatment room.

(10) The registrant shall maintain a record of each quality assurance check required by 41.3(17)*"d"*(1) and (7) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

e. Operating procedures.

(1) Therapeutic radiation machines shall not be left unattended unless secured by means identified in 41.3(17)*"a"*(9)"5";

(2) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

(3) The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

(4) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(5) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of 641—40.26(136C).

f. Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 41.3(17) shall have at its disposal appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μSv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

41.3(18) Therapeutic radiation machines—photon therapy systems (500 kV and above) and electron therapy systems (500 keV and above).

a. Equipment requirements.

(1) Leakage radiation outside the maximum useful beam in photon and electron modes.

1. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum-sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e., patient plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

2. Except for the area defined in 41.3(18)*"a"*(1)"1," the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

3. For equipment manufactured after July 9, 1997, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Agency (IEC) Document 601-2-1 (most current revision); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 41.3(18)*"a"*(1)"1" to "3" for the specified operating conditions. Records of leakage radiation measurements shall be maintained for inspection by the agency.

(2) Leakage radiation through beam-limiting devices.

1. Photon radiation. All adjustable or interchangeable beam-limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam-limiting device(s) shall not exceed 2 percent of the maximum absorbed dose on the central axis of the useful beam measured in a 10-centimeter by 10-centimeter radiation field;

2. Electron radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation including, but not limited to, photon radiation generated by electrons incident on the beam-limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

- A maximum of 2 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and
- A maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.

(3) Measurement of leakage radiation.

1. Photon radiation. Measurements of leakage radiation through the beam-limiting devices shall be made with the beam-limiting devices closed and any residual aperture blocked by at least two-tenth value layers of suitable absorbing material. In the case of overlapping beam-limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector with an area not exceeding ten square centimeters;

2. Electron radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector with an area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent buildup material.

(4) Filters/wedges.

1. Each wedge filter which is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;

2. If the absorbed dose rate information required by 41.3(18)*"a"*(9) relates exclusively to operation with a field-flattening or beam-scattering filter in place, such filter shall be removable only by the use of tools;

3. For equipment manufactured after July 9, 1997, which utilizes a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam-scattering foils:

- Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;
- An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
- A display shall be provided at the treatment control panel showing the wedge filter(s); and
- An interlock shall be provided to prevent irradiation if any filter or beam-scattering foil selection operation carried out in the treatment room does not agree with the filter or beam-scattering foil selection operation carried out at the treatment control panel.

(5) Stray radiation in the useful beam. For equipment manufactured after July 9, 1997, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that X-ray stray radiation in the useful electron beam, absorbed dose at the surface during X-ray irradiation and stray neutron radiation in the useful X-ray beam are in compliance with International Electrotechnical Agency (IEC) Document 601-2-1 (most current revision).

(6) Beam monitors. All therapeutic radiation machines subject to 41.3(18) shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

1. Equipment manufactured after July 9, 1997, shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

2. Equipment manufactured on or before July 9, 1997, shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system. The detector and the system into which that detector is incorporated shall meet the following requirements:

- Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;
- Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;
- Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and

3. For equipment manufactured after July 9, 1997, the design of the beam monitoring systems shall ensure that the:

- Malfunctioning of one system shall not affect the correct functioning of the other system(s); and
- Failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation or prevent the initiation of radiation.

4. Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after July 9, 1997, each display shall:

- Maintain a reading until intentionally reset;
- Have only one scale and no electrical or mechanical scale multiplying factors;
- Utilize a design such that increasing dose is displayed by increasing numbers; and
- In the event of power failure, the beam monitoring information required in 41.3(18)*"a"*(6)"4" displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20-minute period of time.

(7) Beam symmetry.

1. Bent-beam linear accelerators subject to 41.3(18) shall be provided with auxiliary device(s) to monitor beam symmetry;

2. The device(s) referenced in 41.3(18)*"a"*(7)"1" shall be able to detect field asymmetry greater than 10 percent, and shall be configured to terminate irradiation if field asymmetry cannot be maintained at 10 percent or less.

(8) Selection and display of dose monitor units.

1. The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually;

2. After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

3. For equipment manufactured after July 9, 1997, after termination of irradiation, it shall be necessary for the operator to reset the preselected dose monitor units before irradiation can be initiated.

(9) Air kerma rate/absorbed dose rate. For equipment manufactured after July 9, 1997, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. (The radiation detectors specified in 41.3(18)*"a"*(6) may form part of this system.) In addition:

1. The dose monitor unit rate shall be displayed at the treatment control panel;

2. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

3. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 400 rad (4 Gy); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in 41.3(18)*"a"*(7)"2" and "3" for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the agency.

(10) Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy.

1. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system;

2. If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

3. For equipment manufactured after July 9, 1997, an indicator on the control panel shall show which monitoring system has terminated irradiation.

(11) Termination switches. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

(12) Interruption switches. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change of a preselected value is made during an interruption, irradiation and equipment movements shall be automatically terminated.

(13) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

1. A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator;

2. The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(14) Selection of radiation type. Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:

1. Irradiation shall not be possible until a selection of radiation type (X-rays or electrons) has been made at the treatment control panel;

2. The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

3. An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type which has been selected;

4. An interlock system shall be provided to prevent irradiation with X-rays, except to obtain a verification image, when electron applicators are fitted;

5. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted; and

6. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(15) Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

2. The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated; and

3. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.

(16) Selection of stationary beam radiation therapy or moving beam radiation therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

1. Irradiation shall not be possible until a selection of stationary beam radiation therapy or rotational arc radiation therapy has been made at the treatment control panel;

2. The mode of operation shall be displayed at the treatment control panel;

3. An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected;

4. An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

5. Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after July 9, 1997:

- An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of rotation differs by more than 20 percent from the selected value;
- Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5 percent from the dose monitor unit value selected;
- An interlock shall be provided to prevent motion of more than five degrees beyond the selected limits during moving beam radiation therapy;
- An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counterclockwise moving beam radiation therapy.
- Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

6. Where the beam monitoring system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by 41.3(18)*"a"*(10); and

7. For equipment manufactured after July 9, 1997, an interlock system shall be provided to terminate irradiation if movement:

- Occurs during stationary beam radiation therapy; or
- Does not start or stops during moving beam radiation therapy unless such stoppage is a preplanned function.

b. Facility design requirements for therapeutic radiation machines operating above 500 kV. In addition to shielding adequate to meet requirements of 41.3(19), the following design requirements are made:

(1) Protective barriers. All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors.

(2) Control panel. In addition to other requirements specified in 41.3(136C), the control panel shall also:

1. Be located outside the treatment room;

2. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

3. Provide an indication of whether radiation is being produced; and

4. Include an access control (locking) device which will prevent unauthorized use of the therapeutic radiation machine.

(3) Viewing systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(4) Aural communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible.

(5) Room entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF".

(6) Entrance interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel.

(7) Beam interceptor interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 641—paragraphs 40.26(1)*"a"* and *"b,"* interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s).

(8) Emergency cutoff switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by 41.3(18)*"a"*(11)**.** All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch.

(9) Safety interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.

(10) Surveys for residual radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photoneutron production.

(11) Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 41.3(18) shall have at its disposal appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μSv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

c. Radiation therapy physicist support.

(1) The services of a radiation therapy physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The radiation therapy physicist shall be responsible for:

1. Full calibration(s) required by 41.3(18)*"e"* and protection surveys required by 41.3(16)*"a"*;

2. Supervision and review of dosimetry;

3. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

4. Quality assurance, including quality assurance check review required by 41.3(18)*"f"*(5) of these regulations;

5. Consultation with the authorized user in treatment planning, as needed; and

6. Performing calculations/assessments regarding misadministrations.

(2) If the radiation therapy physicist is not a full-time employee of the registrant, the operating procedures required by 41.3(18)*"d"* shall also specifically address how the radiation therapy physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the radiation therapy physicist can be contacted.

d. Operating procedures.

(1) No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

(2) Therapeutic radiation machines shall not be made available for medical use unless the requirements of 41.3(16)*"a,"* 41.3(18)*"e,"* and 41.3(18)*"f"* have been met;

(3) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

(4) When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light field;

(5) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

(6) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

e. Full calibration measurements.

(1) Full calibration of a therapeutic radiation machine subject to 41.3(18) shall be performed by, or under the direct supervision of, a radiation therapy physicist:

1. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

2. Full calibration shall include measurement of all parameters listed in Appendix D of 641—Chapter 41. Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not to exceed 12 calendar months, unless a more frequent interval is required by this agency.

3. Before medical use under the following conditions:

- Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multienergy or multimode capabilities or both shall only require measurements for those modes or energies that are not within their acceptable range; and
- Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes or energies, full calibration shall be performed on the effected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 41.3(18)*"e"*(1)"3."

(2) The registrant shall use the dosimetry system described in 41.3(16)*"c"* to measure the radiation output for one set of exposure conditions.

(3) The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the radiation therapy physicist responsible for performing the calibration.

f. Periodic quality assurance checks.

(1) Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to 41.3(18) at intervals as specified in Appendix D of 641—Chapter 41;

(2) To satisfy the requirement of 41.3(18)"*f*"(1), quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in Appendix D of 641—Chapter 41. Representative sampling shall include all referenced periodic quality assurance checks at intervals not to exceed 12 consecutive calendar months;

(3) The registrant shall use a dosimetry system which has been intercompared within the previous 12 months with the dosimetry system described in 41.3(16)"*c*"(1) to make the periodic quality assurance checks required in 41.3(18)"*f*"(2);

(4) The registrant shall perform periodic quality assurance checks required by 41.3(18)"*f*"(1) in accordance with procedures established by the radiation therapy physicist;

(5) The registrant shall review the results of each periodic radiation output check according to the following procedures:

1. The authorized user and radiation therapy physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the radiation therapy physicist has determined that all parameters are within their acceptable tolerances;

2. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within seven working days; and

3. The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check within 20 working days of completion.

(6) Therapeutic radiation machines subject to 41.3(18) shall have safety quality assurance checks of each external beam radiation therapy machine performed at intervals not to exceed one week;

(7) To satisfy the requirement of 41.3(18)"*f*"(6), safety quality assurance checks shall ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;
2. Proper operation of the "BEAM-ON," interrupt and termination switches;
3. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;
4. Viewing systems;
5. Aural systems;
6. Electrically operated treatment room door(s) from inside and outside the treatment room;

(8) Emergency power cutoff switches shall be checked for proper operation at intervals not to exceed three months. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine;

(9) The registrant shall promptly repair any system identified in 41.3(18)"*f*"(7) that is not operating properly; and

(10) The registrant shall maintain a record of each quality assurance check required by 41.3(18)"*f*"(1) and 41.3(18)"*f*"(7) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

41.3(19) Shielding and safety design requirements.

a. Each therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall be provided with such primary or secondary barriers as are necessary to ensure compliance with 641—40.15(136C) and 641—40.26(136C).

b. Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for agency approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in Appendix E of 641—Chapter 41.

641—41.4(136C) Radiation safety requirements for analytical X-ray equipment. Rescinded IAB 4/8/98, effective 7/1/98.

641—41.5(136C) Radiation safety requirements for wireline service operations and subsurface tracer studies. Rescinded IAB 4/8/98, effective 7/1/98.

641—41.6(136C) X-ray machines used for screening and diagnostic mammography.

41.6(1) *Definitions.* In addition to the definitions provided in 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions shall be applicable to this rule.

"Accreditation body" means an entity that has been approved by FDA to accredit mammography facilities.

"Action limits" or *"action levels"* means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

"Adverse event" means an undesirable experience associated with mammography activities. Adverse events include but are not limited to:

1. Poor image quality;
2. Failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and
3. Use of personnel who do not meet the applicable requirements of this chapter.

"Air kerma" means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For X-rays with energies less than 300 kiloelectronvolts (keV), 1 Gray of absorbed dose is delivered by 114 roentgens (R) of exposure.

"Artifact" means a substance or structure not naturally present in living tissue but of which an authentic image appears in a radiograph.

"Automatic exposure control systems" means automatic exposure control systems, often referred to as phototimers, which are designed to automatically determine and provide the exposure needed to produce an adequate density image by sampling the X-ray intensity after passage through the patient and image receptor.

"Average glandular dose" means the energy deposited per unit mass of glandular tissue averaged over all the glandular tissue in the breast, calculated from values of entrance exposure in air, the X-ray beam quality (half-value layer), and compressed breast thickness. The maximum average glandular dose should be 6 milliGray (0.6 rad) or less for a 2-view examination of the breast. See also: "Dose."

"Breast implant" means a prosthetic device implanted in the breast.

"Calendar quarter" means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.

"Category 1" means medical education activities that have been designated as Category 1 by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society, or an equivalent organization.

"Certificate" means the certificate described in 41.6(2)*"a"*(2).

"Certification" means the process of approval of a facility by the FDA or this agency to provide mammography services.

"Clinical image" means a mammogram.

"Compression device" means a firm plastic paddle used to help hold the breast stationary and eliminate blurring due to motion, to help separate structures within the breast, and to decrease the thickness of breast tissue, minimizing the amount of radiation used and the amount of scattered radiation reaching the film.

"Consumer" means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

"Contact hour" means an hour of training received through direct instruction.

"Continuing education unit" or *"continuing education credit"* means one contact hour of training.

"Craniocaudal view" means one of two routine views for mammography. The detector system is placed caudad to (below) the breast and the vertical X-ray beam is directed from cranial to caudad (downward) through the breast.

"Dedicated mammography equipment" means X-ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and low dose exposure that can generate reproducible images of high quality.

"Direct instruction" means:

1. Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or
2. The administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

"Direct supervision" means that:

1. During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records; or
2. During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

"Dose" means the amount of energy deposited per unit mass of tissue due to X-radiation. The newer unit of absorbed dose is the Gray: 1 Gray=1 Joule of energy deposited per kilogram of tissue. The older unit of absorbed dose is the rad: 1 rad=0.01 Gray, 1 centiGray, or 10 milliGray.

"Exposure" means the amount of X-radiation, quantitated by measuring the amount of ionization in air caused by the radiation. The units of exposure are Coulombs of charge ionized per kilogram of air. The older unit of exposure is the Roentgen: 1 Roentgen=2.58 $\times$ 10E-4 Coulombs of charge per kilogram of air.

"Facility" means a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: operation of equipment to produce a mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. This term does not include a facility of the Department of Veterans Affairs.

"FDA" means the Food and Drug Administration.

"First allowable time" means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body. The "first allowable time" may vary with the certifying body.

"Grids" means a set of thin lead strips spaced close to one another, interspaced by carbon fiber for mammographic grids. The grid is placed between the breast and the screen-film image receptor to reduce scattered radiation reaching the image receptor.

"Image noise." See "Radiographic noise."

"Image receptor support device" means, for mammography X-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

"Interpreting physician" means a licensed radiologist who interprets mammograms and who meets the requirements set forth in 41.6(3)*"a."*

"Kerma" means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

"Laterality" means the designation of either the right or left breast.

"Lead interpreting physician" means the interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of this chapter. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

"Mammogram" means a radiographic image produced through mammography.

"Mammographic modality" means a technology for radiography of the breast. Examples are screen-film mammography, xeromammography, and digital mammography.

"Mammography" means radiography of the breast but, for the purposes of 641—41.6(136C), does not include:

1. Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or
2. Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA investigational device exemption regulations; or
3. Radiography of the breast performed as part of either a breast localization procedure or a post-stereotactic clip placement localization procedure.

"Mammography equipment evaluation" means an on-site assessment of the mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards.

"Mammography medical outcomes audit" means a systematic collection of mammography results and the comparison of those results with outcomes data.

"Mammography unit(s)" means an assemblage of components for the production of X-rays for use during mammography including, at a minimum: an X-ray generator, an X-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.

"Mean optical density" means the average of the optical densities measured using phantom thicknesses of 2, 4, and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

"Medical physicist" means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in 41.6(3)*"c."*

"Mediolateral view" means one of the routine views for mammography in addition to the craniocaudal view. The detector system is placed lateral to the breast and the horizontal X-ray beam is directed from medial to lateral aspect through the breast.

"MQSA" means the Mammography Quality Standards Act of 1992.

"Multi-reading" means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram. A radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

"Oblique mediolateral view" means one of the standard two views of the breast. The detector system (cassette holder assembly) is angled 30-60 degrees from horizontal so that the cassette assembly is parallel to the pectoral muscle and the corner of the cassette holder fits comfortably into the axilla. The X-ray beam is directed from the supero-medial to the infero-lateral aspect of the breast.

"Patient" means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

"Phantom" means an artificial test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

"Phantom image" means a radiographic image of a phantom.

"Physical science" means physics, chemistry, radiation science (including medical physics and health physics), and engineering.

"Positive mammogram" means a mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."

"Qualified instructor" means individuals whose training and experience adequately prepare them to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of 41.6(3) would be considered qualified instructors in their respective areas of mammography. Radiological technologists who meet the requirements of 41.6(3) and have passed a state-approved mammography examination such as the examination given by the American Registry of Radiography Technologists would be considered qualified instructors in their respective areas of mammography. The examination would include, but not necessarily be limited to: breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this chapter include, but are not limited to, instructors in a post-high school training institution and manufacturers' representatives.

"Quality control technologist" means an individual meeting the requirements of 41.6(5)*"a"*(4) who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

"Radiographic equipment" means X-ray equipment used for the production of static X-ray images.

"Radiologic technologist" means an individual specifically trained in the use of radiographic equipment and in the positioning of patients for radiographic examinations and who meets the requirements set forth in 41.6(3)*"b."*

"Radiologist continuing experience" means the number of mammograms interpreted by a radiologist in the past 24-month period. For the purpose of counting, a radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

"Screen-film mammography" means mammography performed with high-detailed intensifying screen(s) in close contact with the film.

"Screening mammography" means X-ray breast examination of asymptomatic individuals in an attempt to detect breast cancer when it is small, nonpalpable, and confined to the breast.

"Serious adverse event" means an adverse event that may significantly compromise clinical outcomes or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

"Serious complaint" means a report of a serious adverse event.

"Standard breast" means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.

"Supplier" means the individual in control of a mammography facility whose basic responsibility is the overall quality of all mammograms conducted in that particular facility.

"Survey" means an on-site physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.

"Time cycle" means the film development time.

"Traceable to a national standard" means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every two years and the results of the proficiency test conducted within 24 months of calibration show agreement within ± 3 percent of the national standard in the mammography energy range.

"Written report" means interpreting physician's technical narrative of a mammography evaluation.

"Written statement" means interpreting physician's description of a mammography examination written in lay terms.

41.6(2) *Registration and application standards and requirements.*

a. Registration and certificates.

(1) Each radiation machine used to perform mammography shall be registered according to 641—subrule 39.3(2).

(2) A certificate issued by the FDA or this agency is required for lawful operation of all mammography facilities subject to the provisions of this subrule. To obtain a certificate from the FDA or this agency, facilities are required to meet the quality standards in 641—41.6(136C) and to be accredited and approved by an approved accreditation body.

b. Each facility wishing to perform mammography shall apply for agency approval by providing or verifying the following information for each mammography machine:

(1) The mammography unit meets the criteria for agency-approved mammography accreditation bodies.

(2) The mammography equipment and facility meet the general requirements of these rules for radiation machines.

(3) The radiation machine is specifically designed to perform mammography.

(4) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(5) The radiation machine is operated by individuals meeting the requirements of this subrule.

(6) The entire mammography system is evaluated annually by a medical physicist.

(7) The equipment, personnel, procedures, and records are evaluated annually by a physician consultant.

(8) Provisional certification. A new facility beginning operation after September 30, 1994, is eligible to apply for provisional certification. This will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process. To apply for and receive provisional certification, a facility must meet the requirements of 641—41.6(136C). Provisional certification shall be effective for up to six months from the date of issuance and cannot be renewed. The facility may apply for a 90-day extension.

c. Withdrawal or denial of mammography certification.

(1) Mammography certification may be withdrawn with cause if any facility or machine does not meet one or more of the standards of these rules, will not permit inspections or provide access to records or information in a timely fashion, or has been guilty of misrepresentation in obtaining the certification.

(2) The facility shall have opportunity for a hearing in connection with a denial or withdrawal of mammography certification in accordance with 641—Chapter 173.

(3) An emergency order withdrawing certification may be issued in accordance with 641—173.31(17A) if the agency finds the radiation unit or facility violates rules that seriously affect the health, safety, and welfare of the public. An opportunity for hearing shall be held within five working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If certification is withdrawn, the radiation machine shall not be used for mammography until reinstated.

(5) If a facility's certification is revoked, no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility in Iowa within two years of the date of revocation.

d. Reinstatement of mammography certification.

(1) An application for reinstatement shall be submitted and processed the same as an initial application.

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application.

(3) A certificate of reinstatement shall be issued only after the agency has inspected the radiation machine and determined that it meets the requirements of these rules.

e. Inspections. The agency shall conduct an inspection of each radiation machine no later than 14 months after initial mammography certification and at least annually thereafter.

f. Determination of the quality of the mammograms produced by facilities. To make the determination each facility will:

(1) Provide at the time of initial registration and at renewal (at least every three years) thereafter, two original (not copies) mammography examinations which meet the following criteria:

1. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with predominantly fatty breast tissue,

2. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with predominantly glandular breast tissue, and

3. Each mammography examination must have been interpreted as a "normal" examination.

(2) Provide randomly (at least every three years), at the request of agency mammography inspectors, two mammography examinations (mammograms) which meet the criteria in 41.6(2)"*f*"(1).

(3) Have the film returned by the agency for inclusion in the patient's file after quality interpretation by agency radiologists.

(4) Be billed the fee for the quality interpretation as set forth in 641—38.8(1)"*b*"(2).

(5) Be provided with a written explanation of the results of the quality evaluation which will accompany the returned mammograms referred to in 41.6(2)"*f*"(3).

g. Federal mammography regulations. All Iowa facilities performing mammography shall comply with the applicable regulations found in 21 CFR Part 900 which has an effective date of April 28, 1999. Persons certified to perform mammography in Iowa shall be responsible for ensuring compliance with the appropriate CFR regulations or Iowa administrative rules, whichever are more stringent.

41.6(3) *Mammography personnel.* The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

a. Interpreting physicians. All radiologists interpreting mammograms shall meet the following qualifications:

(1) Initial qualifications. Unless the exemption in 41.6(3)"*a*"(3)"1" applies, before beginning to interpret mammograms independently, the interpreting radiologist shall:

1. Be licensed to practice medicine in Iowa;

2. Be certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography; or

- Have had at least three months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a radiologist who meets the requirements of 41.6(3)"*a*";

3. Have a minimum of 60 hours of documented medical education in mammography, which shall include: instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be category I and at least 15 of the category I hours shall have been acquired within the three years immediately prior to the date that the radiologist qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to category I continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution; and

4. Unless the exemption in 41.6(3)*"a"*(3)"2" applies, have interpreted or multi-read at least 240 mammographic examinations within the six-month period immediately prior to the date that the radiologist qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician.

(2) Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:

1. Following the second anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)*"a"*(1) were completed, the interpreting physician shall have read or multi-read at least 960 mammographic examinations during the 24 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter immediately preceding the inspection or any date between the two. The facility will choose one of these dates to determine the 24-month period;

2. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)*"a"*(1) were completed, the interpreting physician shall have taught or completed at least 15 category I continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter immediately preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period; and

3. Before an interpreting physician may begin independently interpreting mammograms produced by screen-film or full field digital mammographic modalities, the interpreting physician shall have at least 8 hours of category 1 continuing medical education credits in the mammographic modality. An interpreting physician who has previously qualified to interpret digital mammography in another state will have six months to complete this requirement. The six-month time frame starts when the interpreting physician commences Iowa digital mammography interpretation.

4. Units earned through teaching a specific course can be counted only once towards the 15 required by 41.6(3)*"a"*(2)"2" even if the course is taught multiple times during the previous 36 months.

(3) Exemptions.

1. Those physicians who qualified as interpreting physicians under 41.6(3)*"a"* or FDA interim regulations prior to April 28, 1999, are considered to have met the initial requirements of 41.6(3)*"a."* They may continue to interpret mammograms provided they continue to meet the licensure requirements of 41.6(3)*"a"*(1)"1" and the continuing experience and education requirements of this subrule.

2. Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any six-month period during the last two years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are otherwise exempt from 41.6(3)*"a"*(1)"4."

(4) Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements shall reestablish their qualifications before resuming the independent interpretation of mammograms, as follows:

1. Interpreting physicians who fail to meet the continuing experience requirements of 41.6(3)*"a"*(2)"1" shall:

- Interpret or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician, or

• Interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physician's total to at least 960 examinations for the prior 24 months, whichever is less. The interpretations required under 41.6(3)*"a"*(4)"1" shall be done within the six months immediately prior to resuming independent interpretation. Consecutive or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This agency will determine the validity of such proof and render a decision after review of all pertinent information. Those individuals who are denied requalification will be allowed to resubmit for requalification following a 90-day waiting period.

2. Interpreting physicians who fail to meet the continuing education requirements of 41.6(3)*"a"*(2)"2" shall obtain a sufficient number of additional category I continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

b. Radiologic technologists. All mammographic examinations shall be performed by general radiographers who meet the following general requirements, mammography requirements, and continuing education and experience requirements:

(1) General requirements. Be permitted to operate as a general radiographer in Iowa; and

(2) Mammography requirements. Prior to April 28, 1999, have qualified as a radiologic technologist under 41.6(3)*"b"* or have completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor after successful completion of at least a two-year radiography program. The hours of documented training shall include, but not necessarily be limited to:

1. Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants, and for full field digital mammography training, physics shall be included;

2. The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under 41.6(3)*"b"*; and

3. At least 8 hours of training in each mammography modality to be used by the technologist in performing mammography examinations. The 8 hours shall not include hours derived from performance of supervised examinations; and

(3) Continuing education requirements.

1. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)*"b"*(1) were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period.

2. Units earned through teaching a specific course can be counted only once towards the 15 required in 41.6(3)*"b"*(3)"1" even if the course is taught multiple times during the previous 36 months.

3. Requalification. A radiologic technologist who fails to meet the continuing education requirements of 41.6(3)*"b"*(3)"1" shall obtain a sufficient number of continuing education units in mammography to bring the total up to at least 15 in the previous three years. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

4. Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under 41.6(3)*"b"*(2)"3," the technologist shall have at least 8 hours of continuing education units in the new modality.

(4) Continuing experience requirements.

1. Following the second anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)*"b"*(1) and (2) were completed or October 28, 1999, whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the 24 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.

2. Requalification. Radiologic technologists who fail to meet the continuing experience requirements of this subrule shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist before resuming the performance of unsupervised mammography examinations.

(5) Consecutive or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This agency will determine the validity of such proof and render a decision after review of all pertinent information. Those individuals who are denied requalification will be allowed to resubmit for requalification following a 90-day waiting period.

c. Medical physicists. All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under 41.6(3)*"c"*(2) shall meet the following:

(1) Initial qualifications.

1. Be Iowa approved; and

2. Have a master's degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or 30 quarter hours of college undergraduate or graduate level physics;

3. Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and

4. Have experience conducting surveys in at least one mammography facility and have a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of this subrule; or

(2) Alternative initial qualifications.

1. Have qualified as a medical physicist under FDA interim regulations and have retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and

2. Prior to April 28, 1999, have:

- A bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics,
- Forty contact hours of documented specialized training in conducting surveys of mammography facilities, and
- Have experience conducting surveys in at least one mammography facility and have a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. The training and experience requirements must be met after fulfilling the degree requirement.

(3) Continuing qualifications.

1. Continuing education. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)*"c"*(1) or (2) were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period. Units earned through teaching a specific course can be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.

2. Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of this subrule were completed or April 28, 1999, whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least 6 mammography units during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter immediately preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days can be counted towards this requirement.

3. Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality, that is, a mammographic modality other than one for which the physicist received training to qualify under this subrule, the physicist must receive at least 8 hours of training in surveying units of the new mammographic modality.

(4) Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of this subrule may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists must reestablish their qualifications as follows:

1. Medical physicists who fail to meet the continuing education requirements of this subrule shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous three years.

2. Medical physicists who fail to meet the continuing experience requirements of this subrule shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualifications of this subrule to bring their total surveys up to the required two facilities and 6 units in the previous 24 months. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

d. Retention of personnel records. Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, general radiographers, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and the agency has determined that the facility is in compliance with the MQSA personnel requirements.

41.6(4) *Obtaining and preserving records.*

a. The facility of the current mammography examination must make all reasonable efforts to obtain the patient's recent mammography records, including original images or films, copies of written reports prepared by interpreting physicians, and other relevant information pertinent to previous mammograms that might be available from others, for comparison with the current mammography records.

b. The facility must make, for each patient, a written report of each mammography examination performed. This report shall include:

(1) The date the mammography procedure was performed.

(2) The date of the interpretation.

(3) The name of the interpreting physician.

(4) The name of the patient and an additional patient identifier.

(5) A description of the procedures performed.

(6) The name of the referring physician (if any) or other physician (if any) identified by the patient to receive the interpreting physician's written report.

(7) The date the interpreting physician's written report was sent to the appropriate physician or patient.

(8) A separate and distinct section entitled, "Overall Final Assessment" with findings classified in one of the following categories or an approved equivalent:

1. "Negative": Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained).
2. "Benign": Also a negative assessment.
3. "Probably benign": Finding(s) has a high probability of being benign.
4. "Suspicious": Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant.
5. "Highly suggestive of malignancy": Finding(s) has a high probability of being malignant.
6. In cases where no final assessment category can be assigned due to incomplete workup, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment, and reasons why no assessment can be made shall be stated by the interpreting physician.

(9) Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

c. Preservation of records.

(1) The facility must provide satisfactory assurances (as documented in its medical records) that the images or films of the first and subsequent mammography procedures and the related written reports of the interpreting physician for each patient are either placed in the patient's medical record kept by the facility or sent for placement in the patient's medical record as directed by the patient's physician or the patient.

(2) Records retained by the facility must be retained for at least 60 calendar months following the date of service or not less than ten years, if no additional mammograms of the patient are performed.

(3) If the facility should cease to exist before the end of the 60-month period, the records must be transferred to the patient or patient's physician or other mammographic facility.

(4) The facility shall upon request by, or on behalf of, the patient, permanently or temporarily, transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly.

(5) Any fee charged to the patient for providing the services in subparagraph (4) above shall not exceed the documented costs associated with this service.

d. Communication of results to the patient. Each facility shall maintain a system to ensure that the results of each mammographic examination are communicated in lay terms to each patient in a time period not to exceed 30 days from the date of the mammography examination. If assessments are "Suspicious" or "Highly suggestive of malignancy" and the patient has not named a health care provider, the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(1) As soon as possible, but no later than 30 days from the date of the mammography examination, patients who do not name a health care provider to receive the mammography report shall be sent the report described in 41.6(4)*"e"*(1) in addition to a written notification of results in lay terms.

(2) Each facility that accepts patients who do not have a primary care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

e. Communication of results to health care providers. When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

(1) Provide a written report of the mammography examination, including all of the items listed in 41.6(4)*"b,"* to the health care provider as soon as possible, but no later than 30 days from the date of the examination, and

(2) If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible or, if the health care provider is unavailable, to a responsible designee of the health care provider.

f. Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(1) Name of patient and an additional patient identifier.

(2) Date of examination.

(3) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by the FDA shall be used to identify view and laterality.

(4) Facility name and location. At a minimum, the location shall include the city, state, and ZIP code of the facility.

(5) Technologist identification.

(6) Cassette/screen identification.

(7) Mammography unit identification, if there is more than one unit in the facility.

41.6(5) *Quality assurance program.*

a. The facility shall ensure that the facility has an equipment quality assurance program specific to mammography and covering all components of the system to ensure consistently high-quality images with minimum patient exposure. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

(1) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of these rules. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

(2) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall:

1. Follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and

2. Participate in the facility's medical outcomes audit program.

(3) Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the applicable reports.

(4) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of 41.6(5)*"e"* through *"k."*

b. The facility shall ensure that a general review of the program is conducted at least annually and have available the services of a qualified medical physicist who is capable of establishing and conducting the program.

c. Under the direction of the lead interpreting physician, the medical physicist shall have responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

(1) Conducting or training others to conduct equipment performance monitoring functions.

(2) Analyzing the monitoring results to determine if there are any problems requiring correction.

(3) Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventive maintenance.

d. Calibration of equipment. All variable parameters of the equipment shall be calibrated:

(1) When the equipment is first installed.

(2) After any major changes or replacement of parts.

(3) At least annually during use based on recommendations of the mammography imaging medical physicist.

(4) When quality assurance tests indicate that calibration is needed.

e. Performance monitoring. The supplier shall routinely ensure that the performance of the mammography system is monitored. The parameters to be monitored shall include but not be limited to:

(1) Processor performance (through daily sensitometric-densitometric means).

(2) Half-value layer.

(3) Output reproducibility and linearity.

(4) Automatic exposure control reproducibility and linearity.

(5) Adequacy of film storage (both before use and after exposure if processing does not occur immediately).

(6) Availability and use of technique charts that shall include an indication of the kV-target-filter combination to be used with each image receptor.

(7) Darkroom integrity, to be performed at least semiannually or when conditions have changed, shall include an inspection for light leaks, a fog test, and a safe light test.

(8) Image quality. The minimum image quality achieved at a mammography facility shall be the ability to observe the image of at least four 0.75-mm fibriles, three 0.32-mm speck groups, and three 0.75-mm masses from an FDA-approved phantom (or equivalent) on the standard mammographic film used at the facility. No mammograms shall be performed if this minimum is not met.

f. Frequency of monitoring.

(1) Processor performance shall be accomplished daily before processing patient films.

(2) Image quality shall be monitored at least weekly with a phantom and every time the unit is altered including the replacement of parts.

(3) All other parameters shall be proportional to the expected variability of each parameter, but at least annually.

g. Evaluation of monitoring results.

(1) Standards of image quality giving acceptable ranges of values for each of the parameters tested shall be established to aid in the evaluation. The standards of image quality related to dose shall include a requirement that the mean glandular dose for one craniocaudal view of a 4.5 cm compressed breast (50 percent adipose/50 percent glandular) or equivalent phantom shall not exceed 100 mrad (millirad) for film/screen units with no grids, or 300 mrad for film/screen units with grids.

(2) The monitoring results shall be compared routinely by the facility staff to the standards of image quality in 41.6(5)*"k."* If the results fall outside the acceptable range, the test shall be repeated. If the results continue to be unacceptable, the source of the problem shall be identified and corrected before further examinations are conducted.

h. Retake analysis program.

(1) A program shall be established as a further aid in detecting and correcting problems affecting image quality or exposure.

(2) All retakes shall be logged including date, technologist's name and reason for retake. A retake analysis shall be performed every 250 patients or quarterly, whichever comes first.

(3) If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

i. Medical outcomes audit. Each facility shall establish a system for reviewing outcome data from all mammography performed, including follow-up on the disposition of positive mammograms and correlation of surgical biopsy results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and pathology results, or both, and review of the mammograms taken prior to the diagnosis of a malignancy. Responsibility for each requirement for monitoring shall be assigned to qualified personnel and documented in the facility's records.

(2) Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified, or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be completed within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

(3) Reviewing interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results, notifying other interpreting physicians of the results and the facility aggregate results. If follow-up actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the follow-up.

j. Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, and protection are properly maintained and updated. These quality control records shall be kept for each test specified in these rules until the next annual inspection has been completed and the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

k. Quality assurance—equipment.

(1) Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that clinical films are processed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

1. The base plus fog density shall be within plus 0.03 of the established operating level.
2. The mid-density shall be within plus or minus 0.15 of the established operating level.
3. The density difference shall be within plus or minus 0.15 of the established operating level.

(2) Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

1. The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.
2. The optical density of the film at the center of the phantom image shall not change by more than plus or minus 0.20 from the established operating level.
3. The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by the FDA.

4. The density difference between the background of the phantom and an added test object used to assess image contrast shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.

(3) Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

- Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square centimeter.

(4) Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

1. Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for two minutes while such film is placed on the countertop emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.
2. Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.
3. Compression device performance. A compression force of at least 25 pounds (111 newtons) for 15 seconds shall be provided. Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 25 pounds (111 newtons) and 45 pounds (200 newtons).

(5) Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

1. Automatic exposure control (AEC) performance.

- The AEC shall be capable of maintaining film optical density (OD) within plus or minus 0.15 of the mean optical density when thickness of a homogenous material is varied over a range of 2 to 6 centimeters and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.
- The optical density of the film in the center of the phantom image shall not be less than 1.20.

2. kVp accuracy and reproducibility.

- The kVp shall be accurate within plus or minus 5 percent of the indicated or selected kVp at the lowest clinical kVp that can be measured by a kVp test device, the most commonly used clinical kVp, and the highest available clinical kVp.
- At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

3. Focal spot condition. Facilities shall evaluate focal spot condition only by determining the system resolution.

- Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.
- The bar pattern shall be placed 4.5 centimeters above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 centimeter of the chest wall edge of the image receptor.
- When more than one target material is provided, the measurement above shall be made using the appropriate focal spot for each target material.
- When more than one SID is provided, the test shall be performed at the SID most commonly used clinically.
- Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

• Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode-cathode axis) and width (dimension perpendicular to the anode-cathode axis) shall be within tolerance limits specified in Table 1.

Table 1

Focal Spot Tolerance Limit Nominal Focal Spot Size (mm)	Maximum Measured Dimensions Width (mm)	Length (mm)
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

4. Beam quality and half-value layer (HVL). The HVL shall meet the specification of 41.1(4) and 41.1(6) for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.

Table 2

X-ray Tube Voltage (kilovolt peak) and Minimum HVL Designed Operating Range (kV) Below 50	
Measured Operating Voltage (kV)	Minimum HVL (millimeters of aluminum)
20	0.20
25	0.25
30	0.30

5. Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

6. Dosimetry. The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 0.3 rad (3.0 milligray (mGy)) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

7. X-ray field/light field/image receptor/compression paddle alignment.

• All systems shall have beam-limiting devices that allow the entire chest wall edge of the X-ray field to extend to the chest wall edge of the image receptor and provide means to ensure that the X-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.

• The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than 1 percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall be not be visible on the image.

8. Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

9. System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

10. Radiation output.

- The system shall be capable of producing a minimum output of 800 milliRoentgen (mR) per second (7.0 mGy air kerma per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 centimeters above the breast support surface with the compression paddle in place between the source and the detector.
- The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

11. Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

- An override capability to allow maintenance of compression;
- A continuous display of the override status; and
- A manual emergency compression release that can be activated in the event of power or automatic release failure.

(6) Quality control tests—other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in 41.6(5)*"k"*(5)"6."

(7) Use of test results.

1. After completion of the tests specified in 41.6(5)*"k,"* the facility shall compare the test results to the corresponding specified action limits; or, for non-screen-film modalities, to the manufacturer's recommended action limits; or, for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.
2. If the test results fall outside the action limits, the source of the problem shall be identified, and corrective actions shall be taken before any further examinations are performed or any films are processed using the component of the mammography system that failed the test, if the failed test was that described in 41.6(5)*"k."*

(8) Surveys.

1. At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in 41.6(5)*"k"*(5) and (6), the weekly phantom image quality test described in 41.6(5)*"k"*(2) and the quarterly retake analysis results described in 41.6(5)*"h."*
2. The results of all tests conducted by the facility in accordance with 41.6(5)*"k"*(1) through (7), as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.
3. The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.
4. The survey report shall be sent to the facility within 30 days of the date of the survey.
5. The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

(9) Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.6(5) and 41.6(6). All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of an Iowa-approved medical physicist.

(10) Facility cleanliness.

1. The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and viewbox cleanliness.

2. The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

(11) Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every two years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of plus or minus 6 percent (95 percent confidence level) in the mammography energy range.

(12) Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

1. Comply with all applicable federal, state, and local regulations pertaining to infection control; and

2. Comply with the manufacturer's recommended procedures for the cleaning and disinfecting of the mammography equipment used in the facility; or

3. If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

l. Mammography procedures and techniques for mammography of patients with breast implants.

(1) Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic examination.

(2) Except where contraindicated, or unless modified by a physician's directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.

m. Consumer complaint mechanism. Each facility shall:

(1) Establish a written and documented system for collecting and resolving consumer complaints;

(2) Maintain a record of each serious complaint received by the facility for at least three years from the date the complaint was received;

(3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body and any other appropriate regulatory entity if the facility is unable to resolve a serious complaint to the consumer's satisfaction.

(4) Report unresolved serious complaints to the accreditation body in a manner and time frame specified by the accreditation body.

n. Clinical image quality. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

o. Additional mammography review and patient notification.

(1) If the agency believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the agency, for review by the accreditation body or other entity designated by the agency. This additional mammography review will help the agency to determine whether the facility is in compliance with rule 641—41.6(136C) and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.

(2) If the agency determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a time frame and a manner specified by the agency.

41.6(6) *Equipment standards.* The equipment used to perform mammography shall meet the following standards:

a. Design: Be specifically designed for mammography. This prohibits systems that have been modified or equipped with special attachments for mammography.

b. Performance standards: Meet the Food and Drug Administration (FDA) performance standards for diagnostic X-ray systems and their major components found in 21 CFR 1020.30 and FDA standards for radiographic equipment in 21 CFR 1020.31.

c. Image receptor systems: Have image receptor systems and individual components which are appropriate for mammography and used according to the manufacturer's recommendations.

(1) Systems using screen-film image receptors shall provide, at a minimum, for operation for image receptors of 18×24 centimeters and 24×30 centimeters.

(2) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

(3) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

d. Light fields: For any system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 centimeters or the maximum source-image receptor distance (SID), whichever is less.

e. Magnification:

(1) Systems used to perform noninterventional problem-solving procedures shall have radiographic magnification capability available for use by the operator.

(2) Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

f. Tube-image receptor assembly:

(1) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.

(2) The mechanism ensuring compliance with this subrule shall not fail in the event of power interruption.

g. Film/screen contact: Shall check film/screen contact when cassettes are first placed into use and semiannually thereafter.

h. Focal spot: The focal spot size, magnification factor and source to image receptor distance (SID) shall be appropriate for mammography and in the ranges shown below:

SID	Nominal Focal Spot Size
> 65 cm	< or = to 0.6 mm
50 to 65 cm	< or = to 0.5 mm
< 50 cm	< or = to 0.4 mm

(1) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(2) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(3) When the target material or focal spot, or both, is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material or focal spot, or both, actually used during the exposure.

i. Compression devices: Shall have compression devices parallel to the imaging plane and able to immobilize and compress the breast with a force of at least 25 pounds per square inch and shall be capable of maintaining this compression for at least three seconds. Effective October 28, 2002, each system shall provide:

(1) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

(2) Fine adjustment compression controls operable from both sides of the patient.

(3) Systems shall be equipped with different sized compression paddles that match the sizes of all full field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression"), may be provided. Such compression paddles for special purposes are not subject to 41.6(6)"*i*"(6) and (7).

(4) Except as provided in 41.6(6)"*i*"(5), the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

(5) Equipment intended by the manufacturer's design not to be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

(6) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(7) The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

j. Grids: Shall have the capability for using antiscatter grids.

k. AEC: Shall have automatic exposure control such that:

(1) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.

(2) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

- The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.
- The selected position of the detector shall be clearly indicated.

(3) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

l. Control panel: Shall have a control panel that:

(1) Gives a positive indication when X-rays are being produced.

(2) Gives an audible signal indicating termination of exposure.

(3) Has manual selection of milliampere seconds (mAs) or at least one of its component parts (milliampere (mA) or time, or both).

(4) Has the technique factors (peak tube potential in kilovolts (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure indicated before the exposure begins, except when AEC is used, in which case the technique factors that are set prior to the exposure shall be indicated.

(5) Has a system that, following AEC mode use, shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure.

m. mAs: Shall indicate, or provide a means of determining, the mAs resulting from each exposure made with automatic exposure control.

n. Viewboxes: Shall have a viewbox that is checked periodically to ensure optimal conditions. When the mammogram is placed on the viewbox, the area surrounding the film must be masked to exclude extraneous light which may reduce image contrast.

o. X-ray film: Shall use X-ray film that has been designated by the film manufacturer as appropriate for mammography and that is matched to the screen's spectral output as specified by the manufacturer.

p. Intensifying screens: Shall use intensifying screens that have been designated by the screen manufacturer as appropriate for mammography.

q. Chemicals: Shall use chemical solutions for processing mammography films that are capable of developing the films in a manner equivalent to the minimum requirements specified by the film manufacturer.

r. Hot-lights: Shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the viewbox, available to the interpreting physicians.

s. Masking devices: Shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.

t. Mobile units and vans.

(1) A phantom image shall be produced, processed, and evaluated after each relocation and prior to examinations being conducted.

(2) If processing is not available, a check of the radiation output shall be made and compared to a preset standard for quality. Equipment shall be recalibrated as necessary to maintain quality of phantom image.

41.6(7) *Safety standards for mammography equipment.*

a. Proper safety precautions shall be maintained and shall include, but not be limited to, adequate shielding for patients, personnel, and facilities. The equipment shall be operated only from a shielded position.

b. Equipment operators shall be monitored in accordance with 641—40.37(136C).

c. Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.

d. Equipment shall be shockproof and grounded to protect against electrical hazards.

e. Records of all inspections, reports, and consultations shall be maintained for at least seven years.

RULE 41.6(136C)—APPENDIX I

Rescinded IAB 4/5/00, effective 5/10/00

RULE 41.6(136C)—APPENDIX II
Glandular Dose (in mrad) for 1 Roentgen Entrance Exposure
4.5-cm Breast Thickness—50% Adipose/50% Glandular Breast Tissue*

Mo/Mo Target Filter X-Ray Voltage (kVp)												W/Al Target Filter Combination
HVL	23	24	25	26	27	28	29	30	31	32	33	
0.23	109											
0.24	113	116										
0.25	117	120	122									
0.26	121	124	126	128								
0.27	126	128	130	132	134							
0.28	130	132	134	136	138	139						
0.29	135	137	139	141	142	143	144					
0.30	139	141	143	145	146	147	148	149				170
0.31	144	146	147	149	150	151	152	153	154			175
0.32	148	150	151	153	154	155	156	158	159	160	160	180
0.33	153	154	155	157	158	159	160	162	163	164	164	185
0.34	157	159	160	161	162	163	164	166	167	168	168	190
0.35		163	164	166	167	168	169	170	171	172	172	194
0.36			168	170	171	172	173	174	175	176	176	199
0.37				174	175	176	177	178	178	179	180	204
0.38					179	180	181	182	182	183	184	208
0.39						184	185	186	186	187	188	213
0.40							189	190	191	192	192	217
0.41								194	195	196	196	221
0.42										200	200	225
0.43											204	230
0.44												234
0.45												238

To convert from entrance exposure in air in Roentgen to mean glandular breast dose in millirads, multiply the entrance exposure by the factor shown in the table for the appropriate kVp and beam quality (HVL) combination. For example, a measured entrance exposure of 0.50 Roentgen from a Mo/Mo Target Filter system at 30 kVp with a measured HVL of 0.36-mm aluminum yields an average glandular dose of (0.50 R) × (174 mrad/R) = 87 mrad or 0.87 mGy.

*Wu X. Breast dosimetry in screen-film mammography. In: Barnes GT, Frey GD (eds), Screen film mammography: Imaging considerations and medical physics responsibilities. Madison, WI: Medical Physics Publishing; 159-175, 1991. W/Al conversion factors are derived from fits to data from Stanton L et al. Dosage evaluation in mammography. Radiology 1984; 150:577-584.

641—41.7(136C) X-ray machines used for stereotactically guided breast biopsy.

41.7(1) *Definitions.* In addition to the definitions provided in rules 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions are applicable to this rule.

"Collaborative setting" means a setting in which a qualified radiologist and surgeon (under 41.7(3)*"a"* or 41.7(3)*"c"*) are working together in consultation and in performing stereotactically guided breast biopsies with a common goal of the patient's benefit.

"Stereotactically guided breast biopsy" means a breast biopsy procedure performed with the utilization of a dedicated system which emits ionizing radiation and is designed specifically for that procedure.

"Supervising physician" means the physician designated by the facility/owner to:

1. Evaluate the equipment, personnel, procedures, and records annually; and
2. Establish and conduct the quality assurance program.

41.7(2) *Registration and application standards and requirements.*

a. Each radiation machine used to perform stereotactically guided breast biopsies shall be registered according to 641—subrule 39.3(2).

b. Each facility wishing to perform stereotactically guided breast biopsies shall apply to the agency for authorization by providing or verifying the following information for each machine:

(1) The stereotactically guided breast biopsy equipment and facility meet the general requirements of these rules for radiation machines.

(2) The radiation machine is specifically designed to perform stereotactically guided breast biopsies.

(3) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(4) The radiation machine is operated by individuals meeting the requirements of this rule.

(5) The entire stereotactically guided breast biopsy system is evaluated annually by a radiation physicist who meets the requirements of this rule.

(6) The equipment, personnel, procedures and records are evaluated annually by the supervising physician.

c. Withdrawal or denial of authorization.

(1) Authorization may be withdrawn with cause if any machine does not meet one or more of the standards of these rules.

(2) The facility shall have an opportunity for a hearing in connection with a denial or withdrawal of authorization.

(3) An emergency order withdrawing authorization may be issued if the agency finds the radiation machine or facility violates rules that seriously affect the health, safety and welfare of the public. An opportunity for hearing shall be held within five working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If authorization is withdrawn, the radiation machine shall not be used until reinstated.

d. Reinstatement of authorization.

(1) An application for reinstatement shall be submitted and processed the same as an initial application.

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application.

(3) A certificate of reinstatement shall be issued only after the agency has inspected the radiation machine and facility and determined that they meet the requirements of these rules.

e. Inspections. The agency shall conduct an inspection of each radiation machine no later than 14 months after initial authorization and at least annually thereafter.

41.7(3) *Physicians.* Physicians must be qualified according to the setting and their role in performing stereotactically guided breast biopsies as outlined below.

a. Requirements for a radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must be qualified according to 41.6(3)*"a."*

2. Shall have performed at least 12 stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on stereotactically guided breast biopsies under a physician who is qualified under 41.6(3)*"a"* and has performed at least 24 stereotactically guided breast biopsies.

3. Shall have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy.

4. Shall be responsible for mammographic interpretation, be experienced as noted in "2" above and be experienced in recommendations for biopsy and lesion identification at time of biopsy.

5. Shall be responsible for oversight of all quality control and quality assurance activities.

6. Shall be responsible for the supervision of the radiologic technologist and the medical physicist.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 stereotactically guided breast biopsies per year or requalify as specified above in 41.7(3)*"a"*(1).

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every three years.

b. Requirements for a physician other than a qualified radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must be licensed to practice medicine in Iowa.

2. Must have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy which includes instruction on triangulation for lesion location.

3. Must have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified to interpret mammography according to 41.6(3)*"a"* and has performed at least 24 stereotactically guided breast biopsies.

4. Shall be responsible for post-biopsy management of the patient.

(2) Maintenance of proficiency and CME requirements.

1. Perform or participate in at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 supervised procedures.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every three years.

c. Requirements for a radiologist performing stereotactically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must be qualified according to 41.6(3)*"a."*

2. Initially, must have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy.

3. Initially, must obtain at least 15 hours of CME in breast imaging including benign and malignant breast diseases.

4. Must have performed at least 12 stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified according to 41.6(3)*"a"* and has performed at least 24 stereotactically guided breast biopsies.

5. Must be responsible for mammographic interpretation.

6. Must be responsible for patient selection.

7. Must be responsible for quality assurance activities including medical audit (tracking of number of biopsies done, cancers found, benign lesions, biopsies needing repeat, and complications).

8. Must be responsible for the oversight of all quality control.

9. Must be responsible for the supervision of the radiologic technologist and the medical physicist.

10. Must be responsible for post-biopsy management of the patient which may include referral to a surgeon for a follow-up on certain lesions.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 supervised procedures.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every three years which includes post-biopsy management of the patient.

d. Requirements for a physician other than a qualified radiologist (under 41.7(3)*"c"*) performing stereotactically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must be licensed to practice medicine in Iowa.

2. Must have evaluated at least 240 mammograms per year in the prior two years in consultation with a physician who is qualified according to 41.6(3)*"a."*

3. Initially, must have at least 15 hours of Category 1 CME or 15 hours of training approved by the agency in stereotactically guided breast imaging and biopsy or three years' experience having performed at least 36 stereotactically guided breast biopsies.

4. Must have four hours of Category 1 CME in medical radiation physics.

5. Must have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified according to 41.6(3)*"a"* and has performed at least 24 stereotactically guided breast biopsies.

6. Must be responsible for patient selection.

7. Must be responsible for quality assurance activities including medical audit (tracking of number of biopsies, cancers found, benign lesions, biopsies needing repeat and complications).

8. Must be responsible for oversight of all quality control.

9. Must be responsible for the supervision of the radiologic technologist and the medical physicist.

10. Must be responsible for post-biopsy management of the patient.

(2) Maintenance of proficiency and CME requirements.

1. Continue to evaluate at least 240 mammograms per year in consultation with a physician who is qualified according to 41.6(3)*"a."*

2. Perform at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 supervised procedures.

3. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every three years.

41.7(4) *Medical physicist.*

a. Must be qualified according to 41.6(3)*"c."*

b. Must meet the following initial requirements:

(1) Prior to July 1, 1998, have performed three hands-on stereotactically guided breast biopsy system physics surveys; or one hands-on stereotactically guided breast biopsy system physics survey under the guidance of a medical physicist qualified through 41.7(4)*"a"* and 41.7(4)*"b."*

(2) On or after July 1, 1998, have performed one hands-on stereotactically guided breast biopsy system physics survey under the guidance of a medical physicist qualified to perform stereotactically guided breast biopsy system physics surveys. Have at least one stereotactically guided breast biopsy system physics survey per year after the initial qualifications are met; and three hours of continuing education in stereotactically guided breast biopsy system physics every three years after the initial qualifications are met.

c. Maintenance of proficiency and continuing education requirements.

(1) Have performed at least one stereotactically guided breast biopsy system physics survey per year after the initial qualifications are met or requalify by performing one survey supervised by a qualified medical physicist; and

(2) Have obtained at least three hours of continuing education in stereotactically guided breast biopsy system physics in the previous 36 months after the initial qualifications are met.

41.7(5) *Radiologic technologist.*

a. Must be qualified according to 41.6(3)*"b."*

b. Must meet the following initial requirements:

(1) Five hands-on stereotactically guided breast biopsy procedures on patients under the supervision of a qualified physician or technologist.

(2) Three hours of continuing education in stereotactically guided breast biopsy.

c. Maintenance of proficiency and continuing education requirements.

(1) Have performed an average of at least 12 stereotactically guided breast biopsies per year after initial qualifications are met or requalify by performing 3 stereotactically guided breast biopsies under the supervision of a qualified physician or radiologic technologist.

(2) Have at least three hours of continuing education in stereotactically guided breast biopsy in the previous 36 months after initial qualifications are met.

(3) If a stereotactic radiologic technologist performs only stereotactic procedures, the radiologic technologist must perform at least 100 stereotactic procedures during the 24 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date between the two. The requirements of 41.6(3)*"b"*(4)"1" do not apply in this case.

d. Three hours of continuing education in stereotactically guided breast biopsy every 3 years after initial qualifications are met.

41.7(6) *Obtaining and preserving records.*

a. The facility must make, for each procedure, a record of the service provided including:

(1) The date of the procedure.

(2) The name of the patient.

(3) The name of the radiologic technologists and physicians performing the procedure.

(4) A description of the service provided.

(5) The name of the referring physician, if any.

b. Records retained by the medical facility must be retained for at least ten years.

41.7(7) *Quality assurance program.*

a. The facility shall have an equipment quality assurance program specific to stereotactically guided breast biopsy systems and covering all components of the system to ensure high-quality images with minimum patient exposure.

b. The facility shall ensure that a general review of the program is conducted at least annually and have available the services of a qualified radiation physicist who is capable of establishing and conducting the program.

c. Under the direction of the supervising physician, the radiation physicist shall have the responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

(1) Conducting equipment performance monitoring functions, at least annually, to include:

1. Evaluation of biopsy unit assembly.

2. Evaluation of focal spot.
3. kVp accuracy/reproducibility.
4. Half-value layer measurement.
5. Exposure reproducibility.
6. Breast entrance exposure, average glandular dose.
7. Image quality evaluation.
8. Artifact evaluation.
9. Digital field uniformity.
10. Localization simulation (gelatin phantom) test.
11. Evaluation of the facility's technologist quality control program.

(2) Analyzing the monitoring results to determine if there are any problems requiring correction.

(3) Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventative maintenance.

d. The supervising physician shall have the responsibility for establishing and conducting the quality control program in a facility with a fixed unit. In the case of a mobile stereotactic unit, the owner or designee shall assume the responsibility for establishing and conducting the quality assurance program. The program shall include:

(1) Localization accuracy (daily before use and before using the localization unit after it is adjusted).

(2) Visual checklist (monthly).

(3) Phantom image (weekly).

(4) Compression (semiannually).

(5) Processor sensitometry (daily before use with systems utilizing film).

e. Each facility shall establish a medical audit program to ensure the accuracy and appropriateness of the procedures performed. This program shall include an imaging-pathology correlation for each biopsy performed, an ongoing analysis of biopsy results and periodic review of the utilization of the procedure.

f. Additional evaluations of stereotactic units shall be conducted whenever a new unit is installed, a unit is disassembled and reassembled at the same or a new location, or major components of a stereotactic unit are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.7(7). All problems shall be corrected before the new or changed equipment is put into service for examinations. The stereotactic equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of an Iowa-approved medical physicist.

41.7(8) *Equipment standards.*

a. Be specifically designed for stereotactically guided breast biopsy.

b. Meet the Food and Drug Administration (FDA) standards found in 21 CFR.

41.7(9) *Safety standards.*

a. Proper safety precautions shall be maintained and shall include, but not be limited to, adequate shielding for patients, personnel and facilities. The equipment shall be operated only from a shielded position.

b. Equipment operators shall wear personnel monitors to monitor their radiation exposure.

c. Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.

d. Equipment shall be shockproof and grounded to protect against electrical hazards.

e. Records of all inspections, reports and consultations shall be maintained for at least seven years.

This rule is intended to implement Iowa Code chapter 136C.

CHAPTER 41—APPENDIX A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS (EXCLUDING THERAPY MACHINES)

In order for the agency to provide an evaluation and verification that national standards have been met on shielding requirements for a radiation installation, the following information shall be submitted.

1. The plans should show, as a minimum, the following:

(a) The normal location of the X-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the X-ray control panel.

(b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

(c) The dimensions of the room(s) concerned.

(d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

(e) The make and model of the X-ray equipment, the energy waveform (single phase, three phase, etc.) and the maximum technique factors.

(f) The type of examination(s) or treatment(s) which will be performed with the equipment.

2. Information on the anticipated workload of the X-ray system(s) in mA-minutes per week.

3. If the services of a qualified expert have been utilized to determine the shielding requirements, a report, including all basic assumptions used, shall be submitted with the plans.

CHAPTER 41—APPENDIX B

DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH

1. Space requirements:

(a) The operator shall be allotted not less than 7.5 square feet (0.697 m) of unobstructed floor space in the booth.

(b) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m).

(c) The space shall be allotted excluding any encumbrance by the X-ray control panel, such as overhang, cables, or other similar encroachments.

(d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette will not reach the operator's station in the booth.

2. Structural requirements:

(a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13 m) high.

(b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.

(c) Shielding shall be provided to meet the requirements of 641—Chapter 40.

3. X-ray control placement:

The X-ray control for the system shall be fixed within the booth; and

(a) Shall be at least 40 inches (1.02 m) from any point subject to direct scatter, leakage or primary beam radiation.

(b) Shall allow the operator to use the majority of the available viewing windows or mirrors.

4. Viewing system requirements:

(a) Each booth shall have at least one viewing device which will:

(1) Be so placed that the operator can view the patient during any exposure, and

(2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then outside that door there shall be an "X-ray" warning sign that will be lighted anytime the rotor of the X-ray tube is activated. Alternatively, that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

(b) When the viewing system is a window, the following requirements also apply:

(1) The viewing area shall be at least 1 square foot (0.0929 m^2).

(2) Regardless of size or shape, at least 0.09 m^2 (1 sq ft) of window area must be centered no less than 0.6 m (2 feet) from the open edge of the booth and no less than 1.5 m (5.0 feet) from the floor.

(3) The material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.

(c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of Appendix B, 4(a).

(d) When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements of Appendix B, 4(a), and

(2) There shall be an alternate viewing system as a backup for the primary system.

CHAPTER 41—APPENDIX C

INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation:

1. Name and address of the applicant and, where applicable, the names and addresses of agents within this state.
2. Diseases or conditions for which the X-ray examinations are to be used in diagnoses.
3. A detailed description of the X-ray examinations proposed in the screening program.
4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information. Any person conducting a screening program for cardiac scoring shall conduct screening only on either women over age 45 or men over age 50 who meet any two of the following criteria: family history, smoker, high blood pressure, high cholesterol, obesity (at least 20 pounds overweight), diabetes.
5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the X-ray examinations.
6. An evaluation by a qualified expert of the X-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) does satisfy all requirements of these regulations. The evaluation shall include a measurement of patient exposures from the X-ray examinations to be performed.
7. A description of the diagnostic film quality control program.
8. A copy of the technique chart for the X-ray examination procedures to be used.
9. The qualifications of each individual who will be operating the X-ray system(s).
10. The qualifications of the individual who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.
11. The name and address of the physician who will interpret the radiograph(s) and a copy of the physician's license to practice in Iowa.
12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.
13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X-ray examinations.
14. An indication of the frequency of screening and the duration of the entire screening program.
15. Documentation justifying the reason for the screening. The applicant must submit data which supports the efficacy of the screening test in diagnosing the disease or condition being screened. Data which will be acceptable to the department includes, but is not limited to, the following: (1) the recommendation of a nationally recognized certifying medical or government body; (2) the recommendation of one of the following national organizations: American Cancer Association, American Lung Association, American Heart Association; or (3) medical literature from peer-reviewed journals supporting the screening.
16. The procedures for preventing pregnant individuals from participating in the screening or justification for allowing pregnant individuals to participate.
17. The dates of the screening to include beginning and ending dates.
18. A copy of IRB for a research project or information justifying the research project.

APPENDIX D

QA for Therapeutic Radiation Machines

Frequency	Procedure	Tolerance[a]
Daily	Dosimetry	
	X-ray output constancy	3%
	Electron output constancy[b]	3%
	Mechanical	
	Localizing lasers	2mm
	Distance indicator (ODI)	2mm
	Safety	
	Door interlocks	functional
	Audiovisual monitors	functional
Monthly	Dosimetry	
	X-ray output constancy[c]	2%
	Electron output constancy[c]	2%
	Backup monitor constancy	2%
	X-ray central axis dosimetry parameter (PDD, TAR) constancy	2%
	Electron central axis dosimetry parameter constancy (PDD)	2mm @ therapeutic depth
	X-ray beam flatness constancy	2%
	Electron beam flatness constancy	3%
	X-ray and electron symmetry	3%
	Safety Interlocks	
	Wedge, electron cone interlocks	functional
	Mechanical	
	Light/radiation field coincidence	2mm or 1% on a side[d]
	Gantry/collimator angle indicators	1 degree
	Wedge position	2mm (or 2% change in transmission factor)
	Tray position	2mm
	Applicator position	2mm
	Field size indicators	2mm
	Cross-hair centering	2mm diameter
	Treatment couch position indicators	2mm/1deg
	Latching of wedges, blocking tray	functional
	Jaw symmetry[e]	2mm
	Field Light intensity	functional

[a] The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under the gantry exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values $\pm$ the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

[b] All electron energies need not be checked daily, but all electron energies are to be checked at least twice weekly.

[c] A constancy check with a field instrument using temperature pressure corrections.

[d] Whichever is greater. Should also be checked after change of light field source.

[e] Jaw symmetry is defined as the difference in distance of each jaw from the isocenter.

Frequency	Procedure	Tolerance[a]
Annual	Dosimetry	
	X-ray/electron output calibration constancy	2%
	Field size dependence of X-ray output constancy	2%
	Output factor constancy for electron applicators	2%
	Central axis parameter constancy (PDD, TAR)	2%
	Off-axis factor constancy	2%
	Transmission factor constancy for all treatment accessories	2%
	Wedge transmission factor constancy[f]	2%
	Monitor chamber linearity	1%
	X-ray output constancy vs. gantry angle	2%
	Electron output constancy vs. gantry angle	2%
	Off-axis factor constancy vs. gantry angle	2%
	Arc mode	Mfrs. specs.
	Safety Interlocks	
	Follow manufacturer's test procedures	functional
	Mechanical	
	Collimator rotation isocenter	2mm diameter
	Gantry rotation isocenter	2mm diameter
	Couch rotation isocenter	2mm diameter
	Coincidence of collimetry, gantry, couch axes with isocenter	2mm diameter
	Coincidence of radiation and mechanical isocenter	2mm diameter

[a] The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under the gantry exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values ± the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

[f] Most wedges' transmission factors are field size and depth dependent.

APPENDIX E

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS FOR THERAPY MACHINES

I. All therapeutic radiation machines.

A. Basic facility information including: name, telephone number and agency registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address (including room number if applicable) of the external beam radiation therapy facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

B. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

II. Therapeutic machines up to 150 kV (photons only).

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) or air kerma at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. A facility blueprint/drawing indicating: scale (0.25 inch = 1 foot is typical); direction of north; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the external beam radiation therapy treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with 641—40.15(136C).

D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, entry door(s)) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

III. Therapeutic radiation machines over 150 kV.

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce photons or electrons with a maximum energy in excess of 150 kV or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced (i.e., photon, electron). The target to isocenter distance shall be specified.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. Facility blueprint/drawing (including both floor plan and elevation views) indicating relative orientation of the therapeutic radiation machine, scale (0.25 inch = 1 foot is typical), type(s), thickness and minimum density of shielding material(s), direction of north, the locations and size of all penetrations through each shielding barrier (ceiling, walls and floor), as well as details of the door(s) and maze.

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy (i.e., room may be designed for 6 MV unit although only a 4 MV unit is currently proposed), workload, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier (walls, floor and ceiling) and "allowed" radiation exposure in both restricted and unrestricted areas.

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

IV. Neutron shielding.

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

A. The structural composition, thickness, minimum density and location of all neutron shielding material.

B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluency rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas.

C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition (i.e., restricted and unrestricted areas, entry door(s) and maze) and neutron shielding material utilized in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

D. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

V. References.

A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV" (1976).

B. NCRP Report 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977).

C. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerator" (1984).

These rules are intended to implement Iowa Code chapter 136C.

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